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By: **Delegates Goldwater, Barkley, Barve, Benson, Bobo, Boteler, Boutin, Bromwell, Bronrott, Busch, Conway, Costa, Donoghue, Dumais, Eckardt, Elliott, Gordon, Harrison, Hixson, Hubbard, Jones, Kach, Kaiser, Lee, Mandel, Marriott, McIntosh, Menes, Morhaim, Murray, Nathan-Pulliam, Oaks, Pendergrass, Rosenberg, Rudolph, Smigiel, V. Turner, Vallario, and Weldon**

Introduced and read first time: January 29, 2004  
Assigned to: Health and Government Operations

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A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacy Benefits Management Act**

3 FOR the purpose of prohibiting a person from practicing pharmacy benefits  
4 management in the State unless the person registers with the Secretary of  
5 Health and Mental Hygiene; requiring an applicant to file a certain application,  
6 submit certain documents, and pay a certain fee; providing for the term of the  
7 registration; providing for the renewal of a registration; authorizing the  
8 Secretary to suspend or revoke a registration or deny an application under  
9 certain circumstances; providing for a certain notice and hearing before a  
10 refusal to renew a registration; providing for an appeal to the Health Claims  
11 Arbitration Office; establishing that a pharmacy benefits manager is a fiduciary  
12 and is required to conform to certain standards of conduct; prohibiting a  
13 pharmacy benefits manager from acting as a private review agent under certain  
14 circumstances; requiring a pharmacy benefits manager to perform duties for a  
15 certain purpose and to disclose certain information regarding any conflicts of  
16 interest; requiring a pharmacy benefits manager to provide certain financial  
17 and utilization information requested by a covered entity; permitting a  
18 pharmacy benefits manager to designate certain information as confidential;  
19 providing for the release of certain confidential information by a covered entity  
20 from a pharmacy benefits manager under certain circumstances; requiring a  
21 pharmacy benefits manager to dispense certain prescription drugs in a certain  
22 manner; requiring a pharmacy benefits manager to transfer certain benefits or  
23 payments received to the covered entity under certain circumstances; providing  
24 for a civil penalty; and generally relating to the registration and regulation of  
25 pharmacy benefits managers.

26 BY adding to  
27 Article - Health - General  
28 Section 20-1001 through 20-1009, inclusive, to be under the new subtitle  
29 "Subtitle 10. Pharmacy Benefits Management Act"

1 Annotated Code of Maryland  
2 (2000 Replacement Volume and 2003 Supplement)

3 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
4 MARYLAND, That the Laws of Maryland read as follows:

5 **Article - Health - General**

6 SUBTITLE 10. PHARMACY BENEFITS MANAGEMENT ACT.

7 20-1001.

8 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS  
9 INDICATED.

10 (B) (1) "COVERED ENTITY" MEANS A PERSON THAT OFFERS HEALTH  
11 INSURANCE THAT INCLUDES PRESCRIPTION DRUG AND DEVICE SERVICES TO THE  
12 PLAN'S ENROLLEES.

13 (2) "COVERED ENTITY" INCLUDES SELF-INSURED EMPLOYERS,  
14 INSURERS, UNIONS, AND HEALTH MAINTENANCE ORGANIZATIONS.

15 (C) "ENROLLEE" MEANS A MEMBER, PARTICIPANT, CONTRACT HOLDER,  
16 POLICYHOLDER, OR BENEFICIARY OF A COVERED ENTITY.

17 (D) "GENERIC DRUG" MEANS A CHEMICALLY EQUIVALENT COPY OF A  
18 BRAND-NAME DRUG WITH AN EXPIRED PATENT.

19 (E) "LABELER" MEANS A PERSON THAT RECEIVES PRESCRIPTION DRUGS  
20 FROM A MANUFACTURER OR WHOLESALER AND REPACKAGES THE DRUGS FOR  
21 LATER RETAIL SALE AND HAS A LABELER CODE FROM THE FEDERAL FOOD AND  
22 DRUG ADMINISTRATION UNDER 21 C.F.R. 270.20 (1999).

23 (F) "PHARMACY" HAS THE MEANING STATED IN § 12-101 OF THE HEALTH  
24 OCCUPATIONS ARTICLE.

25 (G) "PHARMACY BENEFITS MANAGEMENT" MEANS:

26 (1) THE PROCUREMENT OF PRESCRIPTION DRUGS AT A NEGOTIATED  
27 RATE FOR DISPENSING WITHIN THIS STATE TO ENROLLEES;

28 (2) THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG  
29 BENEFITS PROVIDED BY A COVERED ENTITY FOR THE BENEFIT OF ENROLLEES; OR

30 (3) THE ADMINISTRATION OF ANY OF THE FOLLOWING SERVICES  
31 RELATED TO PHARMACY BENEFITS:

32 (I) MAIL SERVICE PHARMACY;

1 (II) CLAIMS PROCESSING, RETAIL NETWORK MANAGEMENT, AND  
2 PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION DRUGS DISPENSED TO  
3 COVERED INDIVIDUALS;

4 (III) CLINICAL FORMULARY DEVELOPMENT AND MANAGEMENT  
5 SERVICES;

6 (IV) REBATE CONTRACTING AND ADMINISTRATION;

7 (V) CERTAIN PATIENT COMPLIANCE, THERAPEUTIC  
8 INTERVENTION, AND GENERIC DRUG SUBSTITUTION PROGRAMS; AND

9 (VI) DISEASE MANAGEMENT PROGRAMS.

10 (H) "PHARMACY BENEFITS MANAGER" OR "PBM" MEANS A PERSON THAT  
11 PERFORMS PHARMACY BENEFITS MANAGEMENT IN A CONTRACTUAL OR  
12 EMPLOYMENT RELATIONSHIP FOR A COVERED ENTITY.

13 (I) "PRIVATE REVIEW AGENT" MEANS A PRIVATE REVIEW AGENT REGULATED  
14 UNDER SUBTITLE 10B OF THE INSURANCE ARTICLE.

15 20-1002.

16 (A) A PERSON MAY NOT ENGAGE IN PHARMACY BENEFITS MANAGEMENT IN  
17 THE STATE UNLESS THE PERSON REGISTERS WITH THE SECRETARY.

18 (B) AN APPLICANT FOR REGISTRATION SHALL:

19 (1) SUBMIT TO THE SECRETARY AN APPLICATION ON THE FORM THAT  
20 THE SECRETARY PROVIDES;

21 (2) SUBMIT THE DOCUMENTS THAT THE SECRETARY REQUIRES; AND

22 (3) PAY TO THE SECRETARY AN APPLICATION FEE SET BY THE  
23 SECRETARY.

24 (C) THE SECRETARY SHALL REGISTER EACH APPLICANT THAT MEETS THE  
25 REQUIREMENTS OF THIS SECTION.

26 (D) THE SECRETARY SHALL INCLUDE ON EACH REGISTRATION THAT THE  
27 SECRETARY ISSUES:

28 (1) THE FULL NAME OF THE REGISTRANT;

29 (2) THE LEGAL NAME OF THE BUSINESS;

30 (3) THE CURRENT ADDRESS OF THE REGISTRANT;

31 (4) THE DATE OF ISSUANCE OF THE REGISTRATION; AND

32 (5) THE DATE THE REGISTRATION EXPIRES.

1 (E) EACH REGISTRANT SHALL GIVE THE SECRETARY WRITTEN NOTICE OF  
2 ANY CHANGE OF ADDRESS WITHIN 10 BUSINESS DAYS AFTER THE CHANGE.

3 (F) (1) UNLESS A REGISTRATION IS RENEWED FOR A 4-YEAR TERM AS  
4 PROVIDED IN THIS SECTION, THE REGISTRATION EXPIRES ON JUNE 1 OF THE FIRST  
5 ODD-NUMBERED YEAR AFTER THE EFFECTIVE DATE OF THE REGISTRATION.

6 (2) AT LEAST 1 MONTH BEFORE A REGISTRATION EXPIRES, THE  
7 SECRETARY SHALL MAIL TO THE REGISTRANT:

8 (I) A RENEWAL APPLICATION FORM; AND

9 (II) A NOTICE THAT STATES:

10 1. THE DATE ON WHICH THE CURRENT REGISTRATION  
11 EXPIRES;

12 2. THE DATE BY WHICH THE SECRETARY MUST RECEIVE  
13 THE RENEWAL APPLICATION FOR THE RENEWAL TO BE ISSUED AND MAILED BEFORE  
14 THE REGISTRATION EXPIRES; AND

15 3. THE AMOUNT OF THE RENEWAL FEE.

16 (3) BEFORE THE REGISTRATION EXPIRES, THE REGISTRANT MAY  
17 PERIODICALLY RENEW FOR AN ADDITIONAL 4-YEAR TERM, IF THE REGISTRANT:

18 (I) OTHERWISE IS ENTITLED TO BE REGISTERED; AND

19 (II) PAYS TO THE SECRETARY A RENEWAL FEE AS SET BY THE  
20 SECRETARY.

21 20-1003.

22 (A) SUBJECT TO THE HEARING PROVISIONS OF SUBSECTION (C) OF THIS  
23 SECTION, THE SECRETARY MAY DENY REGISTRATION TO ANY APPLICANT,  
24 REPRIMAND ANY REGISTRANT, FINE ANY REGISTRANT, OR SUSPEND OR REVOKE A  
25 REGISTRATION IF THE APPLICANT OR REGISTRANT:

26 (1) FRAUDULENTLY OR DECEPTIVELY OBTAINS OR ATTEMPTS TO  
27 OBTAIN A REGISTRATION FOR THE APPLICANT OR REGISTRANT OR FOR ANOTHER;

28 (2) FRAUDULENTLY OR DECEPTIVELY USES A REGISTRATION;

29 (3) HAS A SIMILAR LICENSE OR REGISTRATION DENIED, SUSPENDED, OR  
30 REVOKED IN ANOTHER JURISDICTION;

31 (4) PLEADS GUILTY OR NOLO CONTENDERE TO OR IS CONVICTED OF A  
32 FELONY, THEFT OFFENSE, OR CRIME OF MORAL TURPITUDE;

33 (5) AIDS AN INDIVIDUAL IN FRAUDULENTLY OR DECEPTIVELY  
34 OBTAINING OR ATTEMPTING TO OBTAIN A REGISTRATION UNDER THIS TITLE;

1 (6) WHILE NOT REGISTERED AS A PBM AND EMPLOYED BY OR UNDER  
2 CONTRACT WITH A COVERED ENTITY, SOLICITS TO ENGAGE IN OR WILLFULLY  
3 ENGAGES IN PHARMACY BENEFITS MANAGEMENT;

4 (7) WHILE NOT REGISTERED AS A PBM AND EMPLOYED BY OR UNDER  
5 CONTRACT WITH A COVERED ENTITY, WILLFULLY ADVERTISES AS A PBM;

6 (8) WILLFULLY MAKES A FALSE STATEMENT OR MISREPRESENTATION  
7 IN ANY RENEWAL APPLICATION OR IN ANY OTHER DOCUMENT THAT THE  
8 SECRETARY REQUIRES TO BE SUBMITTED; OR

9 (9) VIOLATES ANY OTHER PROVISION OF THIS SUBTITLE.

10 (B) BEFORE THE SECRETARY DENIES THE REGISTRATION OF AN APPLICANT  
11 UNDER SUBSECTION (A) OF THIS SECTION, THE SECRETARY SHALL CONSIDER THE  
12 FOLLOWING FACTORS:

13 (1) THE LENGTH OF TIME THAT HAS PASSED SINCE THE APPLICANT  
14 PLEADED GUILTY OR NOLO CONTENDERE OR WAS CONVICTED OF THE FELONY,  
15 THEFT OFFENSE, OR CRIME OF MORAL TURPITUDE;

16 (2) WHETHER THE APPLICANT WAS A PBM PRIOR TO THE REQUIREMENT  
17 OF REGISTRATION UNDER THIS SUBTITLE; AND

18 (3) ANY EVIDENCE THAT THE APPLICANT HAS BEEN A GOOD CITIZEN  
19 SINCE THE APPLICANT PLEADED GUILTY OR NOLO CONTENDERE OR WAS  
20 CONVICTED OF THE FELONY, THEFT OFFENSE, OR CRIME OF MORAL TURPITUDE.

21 (C) (1) BEFORE THE SECRETARY TAKES ANY FINAL ACTION UNDER  
22 SUBSECTION (A) OF THIS SECTION, THE SECRETARY SHALL GIVE THE APPLICANT OR  
23 REGISTRANT AGAINST WHOM THE ACTION IS CONTEMPLATED AN OPPORTUNITY FOR  
24 A HEARING BEFORE THE SECRETARY.

25 (2) THE SECRETARY SHALL GIVE NOTICE AND HOLD THE HEARING IN  
26 ACCORDANCE WITH TITLE 10, SUBTITLE 2 OF THE STATE GOVERNMENT ARTICLE.

27 (3) THE HEARING NOTICE TO BE GIVEN TO THE APPLICANT OR  
28 REGISTRANT SHALL BE SENT BY CERTIFIED MAIL TO THE LAST KNOWN ADDRESS OF  
29 THE APPLICANT OR REGISTRANT AT LEAST 10 BUSINESS DAYS BEFORE THE  
30 HEARING.

31 (4) THE SECRETARY MAY ADMINISTER OATHS IN CONNECTION WITH  
32 ANY PROCEEDING UNDER THIS SECTION.

33 (5) THE APPLICANT OR REGISTRANT MAY BE REPRESENTED AT THE  
34 HEARING BY COUNSEL.

35 (6) IF, AFTER DUE NOTICE, THE APPLICANT OR REGISTRANT AGAINST  
36 WHOM THE ACTION IS CONTEMPLATED FAILS OR REFUSES TO APPEAR, THE  
37 SECRETARY MAY, NEVERTHELESS, HEAR AND DETERMINE THE MATTER.

1 (D) ANY APPLICANT OR REGISTRANT AGGRIEVED BY A FINAL DECISION OF  
2 THE SECRETARY MAY TAKE AN APPEAL TO THE HEALTH CLAIMS ARBITRATION  
3 OFFICE.

4 20-1004.

5 A PBM IS A FIDUCIARY AND SHALL ACT:

6 (1) IN GOOD FAITH;

7 (2) IN A MANNER THAT IS REASONABLY BELIEVED TO BE IN THE BEST  
8 INTEREST OF THE COVERED ENTITY AND THE COVERED ENTITY'S ENROLLEES;

9 (3) WITH CARE, SKILL, PRUDENCE, AND DILIGENCE; AND

10 (4) IN ACCORDANCE WITH THE STANDARDS OF CONDUCT APPLICABLE  
11 TO A FIDUCIARY IN AN ENTERPRISE OF LIKE CHARACTER AND WITH LIKE AIMS.

12 20-1005.

13 (A) A PBM SHALL:

14 (1) PERFORM ITS DUTIES FOR THE COVERED ENTITY FOR THE PURPOSE  
15 OF PROVIDING BENEFITS TO ENROLLEES AND DEFRAYING REASONABLE EXPENSES  
16 OF ADMINISTERING HEALTH SERVICES; AND

17 (2) DISCLOSE IN WRITING TO THE COVERED ENTITY ANY ACTIVITY,  
18 POLICY, OR PRACTICE THAT DIRECTLY OR INDIRECTLY PRESENTS ANY CONFLICT OF  
19 INTEREST WITH THE DUTIES IMPOSED BY THIS SUBTITLE.

20 (B) A PBM MAY NOT ACT AS A PRIVATE REVIEW AGENT WHILE PERFORMING  
21 ITS DUTIES AS A PBM.

22 20-1006.

23 (A) A PBM SHALL PROVIDE TO THE COVERED ENTITY ALL FINANCIAL AND  
24 UTILIZATION INFORMATION REQUESTED BY THE COVERED ENTITY RELATING TO:

25 (1) THE PROVISION OF BENEFITS TO ENROLLEES THROUGH THE  
26 COVERED ENTITY; AND

27 (2) ALL FINANCIAL AND UTILIZATION INFORMATION RELATING TO  
28 SERVICES TO THE COVERED ENTITY.

29 (B) (1) THE PBM MAY DESIGNATE ANY FINANCIAL AND UTILIZATION  
30 INFORMATION PROVIDED TO THE COVERED ENTITY BY THE PBM AS CONFIDENTIAL.

31 (2) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION,  
32 CONFIDENTIAL INFORMATION PROVIDED TO A COVERED ENTITY BY A PBM MAY NOT  
33 BE DISCLOSED BY THE COVERED ENTITY TO ANY PERSON WITHOUT THE WRITTEN  
34 CONSENT OF THE PBM.

1 (3) A COVERED ENTITY MAY DISCLOSE INFORMATION DESCRIBED IN  
2 PARAGRAPH (1) OF THIS SUBSECTION:

3 (I) TO THE EXTENT THAT DISCLOSURE MAY BE NECESSARY TO  
4 CARRY OUT THE PURPOSES OF THIS SUBTITLE;

5 (II) WITH THE EXPRESS WRITTEN CONSENT OF THE PBM;

6 (III) UNDER STATUTE OR COURT ORDER FOR THE PRODUCTION OR  
7 DISCOVERY OF EVIDENCE; OR

8 (IV) IF THE INFORMATION IS PERTINENT TO A CLAIM OR IN  
9 LITIGATION.

10 20-1007.

11 (A) A PBM SHALL DISPENSE A SUBSTITUTE PRESCRIPTION DRUG FOR A  
12 PRESCRIBED DRUG ONLY TO AN ENROLLEE ACCORDING TO THE PROVISIONS OF THIS  
13 SECTION.

14 (B) A PBM MAY SUBSTITUTE A LOWER-PRICED GENERIC AND  
15 THERAPEUTICALLY EQUIVALENT DRUG FOR A HIGHER-PRICED PRESCRIBED DRUG.

16 (C) (1) A PBM MAY SUBSTITUTE A HIGHER-PRICED PRESCRIBED DRUG FOR  
17 A LOWER-PRICED GENERIC DRUG ONLY FOR MEDICAL REASONS THAT BENEFIT THE  
18 ENROLLEE AND THE COVERED ENTITY.

19 (2) IF A SUBSTITUTION IS BEING MADE UNDER PARAGRAPH (1) OF THIS  
20 SUBSECTION, A PBM SHALL:

21 (I) DISCLOSE TO THE ENROLLEE AND THE COVERED ENTITY THE  
22 COST OF BOTH DRUGS AND ANY BENEFIT OR PAYMENT DIRECTLY OR INDIRECTLY  
23 ACCRUING TO THE PBM AS A RESULT OF THE SUBSTITUTION; AND

24 (II) OBTAIN THE WRITTEN APPROVAL OF THE ENROLLEE'S  
25 PRESCRIBING HEALTH PROFESSIONAL OR THE ENROLLEE'S AUTHORIZED  
26 REPRESENTATIVE.

27 (D) THE PBM SHALL TRANSFER IN FULL TO THE COVERED ENTITY ANY  
28 BENEFIT OR PAYMENT RECEIVED IN ANY FORM BY THE PBM AS A RESULT OF A  
29 PRESCRIPTION DRUG SUBSTITUTION UNDER SUBSECTION (C) OF THIS SECTION.

30 20-1008.

31 (A) A PBM THAT DERIVES ANY PAYMENT OR BENEFIT FOR THE DISPENSING  
32 OF PRESCRIPTION DRUGS WITHIN THE STATE BASED ON VOLUME OF SALES FOR  
33 CERTAIN PRESCRIPTION DRUGS OR CLASSES OR BRANDS OF DRUGS WITHIN THE  
34 STATE SHALL PASS THE PAYMENT OR BENEFIT ON IN FULL TO THE COVERED  
35 ENTITY.

1 (B) A PBM SHALL DISCLOSE TO THE COVERED ENTITY ALL FINANCIAL TERMS  
2 AND ARRANGEMENTS FOR REMUNERATION OF ANY KIND THAT APPLY BETWEEN  
3 THE PBM AND ANY PRESCRIPTION DRUG MANUFACTURER OR LABELER, INCLUDING:

4 (1) FORMULARY MANAGEMENT AND DRUG-SWITCH PROGRAMS;

5 (2) EDUCATIONAL SUPPORT;

6 (3) CLAIMS PROCESSING AND PHARMACY NETWORK FEES THAT ARE  
7 CHARGED BY RETAIL PHARMACIES; AND

8 (4) DATA SALES FEES.

9 20-1009.

10 THE SECRETARY MAY ASSESS A CIVIL PENALTY, NOT EXCEEDING \$10,000,  
11 AGAINST ANY PERSON WHO VIOLATES THIS SUBTITLE.

12 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
13 October 1, 2004.